K012745

510(k) Summary of Safety and Effectiveness

JAN 1 0 2002

Triage® TOX Drug Screen

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: (To be determined)

A. Name and Address of Submitter

Company Name:	Biosite Incorporated
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Contact Person:	Jeffrey R. Dahlen, Ph.D.
Date Summary Prepared:	8/15/01

B. Device Names

1. Trade Name

   Triage® TOX Drug Screen

2. Common / Usual Name

   Test System for Drugs of Abuse

3. Classification Name

   Amphetamine test system

   Barbiturate test system

   Benzodiazepine test system

   Cocaine and cocaine metabolite test system

   Opiate test system

   Cannabinoid test system

   Methamphetamine test system

   Tricyclic antidepressant drugs test system

Phencyclidine test system (Note: the phencyclidine test system has not been classified but has the same intended use to measure phencyclidine in serum or urine.

C. Predicate Devices

Comparison to reference methods such as GC/MS and HPLC.

D. Device Description and Intended Use

The Triage® TOX Drug Screen is a fluorescence immunoassay intended for use in the semi-quantitative or qualitative determination of major metabolites of amphetamines, methamphetamines, barbiturates, benzodiazepines, cocaine, opiates, phencyclidine, THC, and tricyclic antidepressants in urine.

E. Summary of Performance Data

Analytical Sensitivity: In all cases, the analytical sensitivity was below the reportable range of the test.

Interfering Substances: Substances that are commonly in human urine were tested for interference with results in samples spiked with drug 25% above the threshold concentration and samples spiked with drug 25% below the threshold concentration. None of the substances tested caused interference with the assay results.

Specificity/Cross-reactivity: Drugs and related substances were added to drug-free urine and tested using the Triage® TOX Drug Screen to determine the concentration that produces a positive result. The results are described in the labeling.

Imprecision: Imprecision was determined by measuring three contrived specimens with drug added at approximately 25% below the threshold concentration, the threshold concentration, and 25% above the threshold concentration. Each specimen was evaluated at three external sites by individuals without training as clinical laboratorians. The within-day and total imprecision for each analyte are described in the labeling.

Threshold: Previously established thresholds (amphetamines 1000, methamphetamines 1000, barbiturates 300, benzodiazepines 300, tricyclic antidepressants 1000, phencyclidine 25, opiates 300, cocaine 300, and THC 50) were challenged by testing specimens containing each drug or drug metabolite spiked into drug-free urine at concentrations in increments of 25%

above and 25% below the threshold. Each specimen was tested using the Triage® TOX Drug Screen. The data paralleled the expected agreement based on the coefficient of variation of the assays.

F. Conclusion

The results of performance studies demonstrate that the Triage® TOX Drug Screen is a safe and effective method for the semi-quantitative or qualitative evaluation of drugs of abuse in urine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 5 2002

Jeffery R. Dahlen, Ph.D.
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Clinical & Regulatory Affairs
Biosite Diagnostics
11030 Roselle Street
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Re: k012745
Trade/Device Name: Triage® TOX Drug Screen
Regulation Number: 21 CFR 862.3100; 21 CFR 862.3250; 21 CFR 862.3870; 21 CFR 862.3650; 21 CFR 862.3150; 21 CFR 862.3170; 21 CFR 862.3610; 21CFR 862.3910
Regulation Name: Amphetamine test system; Cocaine and cocaine metabolite test system; Cannabinoid test system; Opiate test system; Barbiturate test system; Benzodiazepine test system; Methamphetamine test system; Tricyclic antidepressant test system
Regulatory Class: Class II
Product Code: DKZ; DIO; LDJ; DJG; DIS; JXM; LAF; LCM; MLK
Dated: November 16, 2001
Received: November 19, 2001

Dear Dr. Dahlen:

This letter corrects the substantially equivalent letter dated January 10, 2002, regarding the incorrect regulation number, the incorrect regulation name and the incorrect indications for use.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~(to be determined)~~ K012745

Device Name: Triage® TOX Drug Screen

Indications For Use:

The Triage® TOX Drug Screen is a fluorescence immunoassay intended to be used with the Triage® Meter for the point-of-care semi-quantitative or qualitative determination of major metabolites of amphetamines, methamphetamines, barbiturates, benzodiazepines, cocaine, opiates, phencyclidine, THC, and tricyclic antidepressants in urine.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012745

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use___

(Optional Format 1-2-96)